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Hearing community voices: public engagement in Australian human embryo research policy, 2005–2007

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This paper investigates the recent public policy processes in Australia with regard to embryo research, including the work of the legislative review committee, parliamentary debates, and the production of the National Health and Medical Research Council guidelines for embryo research. We examine various mechanisms used during each of these policymaking stages to engage various publics, and the procedures for balancing conflicting values, which were particularly evident given the strong promotion of biotechnology investment by government side by side with vigorous opposition to certain technologies by segments of the Australian community. We explore the ethical and democratic challenges posed by developments in embryo research as well as various difficulties that arose in engaging the Australian public during these policymaking processes, whether these might prove to be impediments to the development of justifiable and legitimate life sciences research policy in Australia, and what the future prospects are for adequate public engagement in these contentious areas.

Keywords: public engagement; embryo research policy; deliberative democracy

In liberal democracies, the task of formulating public policy is complicated by the need to take account of the range of values present in heterogeneous societies. These values are often inadequately articulated using standard forms of political representation, and hence various types of public engagement are used, such as public submissions, focus groups, surveys or polls, citizens' juries, and consensus conferences. Although public engagement can have different goals, including education, gaining public trust in or acceptance of emerging technologies, or influencing the direction of scientific research, we focus on its use as part of policymaking processes because of the centrality of public engagement to claims about what makes justifiable and legitimate policy. Citizens now play an indispensable role in generating politically relevant knowledge; arguably, their views are treated as seriously, or more so, than those of professional experts (Delli Carpini *et al.* 2004, Jasanoff 2004). Standard forms of scientific and political authority have been

drawn into question, as many emerging technologies are controversial primarily because of conflicts in how they are evaluated and valued. Hence, policies failing to take account of public values run a serious risk of lack of legitimacy and credibility (Irwin and Wynne 1996). This paper contributes to the consideration of new trajectories for the governance of the life sciences by focusing on public engagement in Australia about human embryo research. It explores attempts to draw citizens into deliberation about controversial issues in life sciences research and assesses the practices and outcomes of a series of specific attempts at public engagement in order to suggest future directions for more adequate public involvement in life sciences governance.

As early as 2001 in Australia, there were explicit calls for public engagement about issues associated with human embryo research. These focused on strategies to involve "the public" in discussion and deliberation about ethically contentious issues, to seek input on relevant policy in this field, and to foster well-informed policy debate (for example, Andrews Report 2001, Knowles 2002). Australian federal and state governments have adopted the position that areas which involve ethically contentious issues, such as abortion, euthanasia, and reproductive technologies, need to be addressed in a different manner from other areas of health policy. Public engagement processes are considered necessary and pursued through a range of strategies: special hearings or legislative review processes; "conscience" votes on legislation; or regulation through bodies with explicit responsibility for providing ethical guidance.

In the case of the regulation of human embryo research, all three of these strategies were utilized. The Research Involving Human Embryos Act (2002) and the Prohibition of Human Cloning Act (2002) included clauses requiring the establishment of a legislation review committee to recommend amendments to the legislation. Thus, the first strategy was the establishment of a legislative review of the 2002 Acts. This review occurred in 2005, leading to recommendations for amendments to the 2002 Acts. The vote on the amending legislation, the 2006 Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryos Research Amendment Act 2006 involved each major political party granting a conscience vote. In this way, the second strategy for addressing ethically contentious policy issues was deployed, by releasing politicians from party restrictions. The third strategy, regulation through bodies with jurisdiction over ethical matters, was also deployed. In 2007, the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) was required to revise its *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (NHMRC 2004) because of amended Commonwealth legislation.

One reason for singling out these areas of policy for extraordinary processes may be genuine uncertainty about public attitudes on the issues, or about how the issues will affect citizens' lives. Governments may then seek input from citizens and other stakeholders through more direct means than political representation. Further, where governments recognize that the issues involved are not likely to generate consensus or near consensus, they may wish to explore the reasoning given for alternative positions to assess which views are defensible, which are inconsistent with democratic respect, and which may be misinformed or not viable. In other words, governments may be

seeking a source of legitimacy for regulation, grounded in policy informed by the best available justification, which reflects informed opinion about the state of the science and current public values.

This paper investigates the recent informal and formal Australian public policy processes with reference to human embryo research, and the degree to which they were structured to listen and respond to plural and conflicting values among Australian citizens. We examine the mechanisms used to engage various publics and the procedures for balancing conflicting values. We also explore structural and other difficulties that arose as publics were engaged during these processes, and the resulting impediments to the development of justifiable and legitimate policy. We are concerned with the ways in which diverse views were sought to articulate the reasoning processes underlying the regulatory decision-making, and the privileging of certain vantage points that may have been built into the processes. In addition, we analyze the degree to which policymakers attempted to respond to the divergent opinions reflected in the public and political engagement over policy decisions. We draw explicitly on the resurgence of interest in political theory on issues of deliberation, public reason, civic engagement, representation, and legitimacy (see Hindmarsh and Du Plessis, Introduction this issue; also Gutmann and Thompson 1996, 2003, Dagger 1997, Dryzek 2000, Young 2000, Fishkin 2002, Mansbridge 2003).

But what makes policy legitimate?

Public engagement, stakeholder involvement, and the testing of competing arguments for policy recommendations are each characteristic of an approach to democratic political legitimacy that seeks to move beyond the purely formal processes characteristic of aggregative democracy. Conventionally, government policy is deemed legitimate if bureaucratic "experts" acting on the authority of a duly elected political representative decide it, or if it is made through a process of a duly elected representative legislature (Mansbridge 1980, Young 2000). These formal processes may be complemented by opportunities for all affected members of a polity (normally citizens) to shape the policy, hence promoting participation in the decision-making. Attempts to achieve this type of participation usually involve explicit efforts by citizens, often acting in groups, or through their representatives to arrive at policy recommendations by means of inclusive, informed, transparent, and accountable processes of collective reasoning. The aim of such processes of collective reasoning is to allow outcomes to be recognized as having been fairly decided through the criterion known as deliberation. Through such processes, public justification (understood as publicly defensible argument) for policy is constructed. These processes also can make explicit who is affected and what is actually at stake for them, hence creating participatory legitimacy. Participatory legitimacy is based on the idea that everyone likely to be affected by policy should have the effective opportunity to air his or her views and concerns as part the policymaking process. For those using this deliberative democratic approach to policymaking, legitimacy is closely tied to the degree

to which those affected can shape policy and the quality of collective reasoning used in public decision-making. This approach involves the legitimation of policy through the transformation of interests via processes of

> collective decision making by all those who will be affected by the decision or their representatives: this is the democratic part. Also ... it includes decision making by means of arguments offered by and to participants who are committed to the values of rationality and impartiality: this is the deliberative part. (Elster 1998, p. 8)

For deliberative legitimacy to be reached in a contentious regulatory domain, public and stakeholder input is needed so that policymakers can avoid the risk of pre-judging policy outcomes. In the case of human embryo research, there is uncertainty about the diversity and intensity of citizens' values and concerns, particularly about the potential benefits and risks of the technologies. Information is limited about how citizens' current values may be affected by potential scientific and social developments. Assessment of embryo research regulation also requires adequate knowledge of the current state of the science, including areas that are contested and in dispute. Therefore, policymakers need to have access to a diversity of scientific, social, legal, and cultural information for policy formation in ethically contentious domains to claim legitimacy.

Based on these considerations, we outline the characteristics necessary for a policy process to claim some level of deliberative, participatory, and justificatory legitimacy, as legitimacy is never all or nothing but a matter of degree. These characteristics are used in subsequent sections of this paper to analyze the policy processes that occurred in Australia in 2005–2007 with regard to embryo research. The involvement of the public and various stakeholders needs to be characterized by inclusive engagement without presumptions about who should count as stakeholders and where traditionally excluded or oppressed voices are recognized and included (Young 2000). Second, there needs to be adequate citizen participation in the policy process to ensure that it is informed by the values, concerns, and arguments of those who are affected. Third, policymakers need to ensure that the input they receive is well informed and reflects current knowledge of the technical and social aspects of the issues through a suitably critical approach to the promotion of public understanding of science (Irwin 1995). Fourth, the process of soliciting input from various publics and stakeholders should occur as a form of discursive participation, where participants give reasons and respond to counter-positions offered, rather than being framed as an adversarial contest with one correct answer.

These strategies are directed at achieving outcomes broadly viewed as defensible, rather than one group "winning" the argument (Gambetta 1998, Dryzek 2000). Public and stakeholder participation needs to occur under conditions of respectful deliberation based on well-placed public trust that public engagement processes will affect policy outcomes, rather than serving as a perfunctory consultation process that at best allows for the venting of opinion – what Alan Irwin has referred to as "public talk" (2006, p. 318). Finally, policy recommendations should include not only the outcomes of deliberative processes, but also justifications for those outcomes, thus allowing the underlying

reasoning to be open to challenge in light of changing information or developments (contestable justification) (Ivison 2002). Where a policy on ethically contentious issues has been formulated through processes of deliberation and where the justification of policy relies on certain social, scientific, or legal circumstances, built-in processes for policy review allow deliberations to be re-opened if these circumstances change.

We now turn to evaluating three of the key policy processes in Australia relating to human embryo research: (1) the legislative review committee process; (2) the parliamentary conscience votes; and (3) the development of the NHMRC guidelines.

The legislative review committee process

In late 2002, both houses of the Australian Parliament passed the Research Involving Human Embryos Act and the Prohibition of Human Cloning Act.[1] Together, these Acts prohibited all human cloning and allowed licenses to be granted for experimentation only on supernumerary embryos created before 5 April 2002. This was consistent with agreements in April 2002 by Australian state health ministers to foster a nationally consistent regulation scheme to govern embryo research (COAG 2002). Deliberate creation of human embryos intended only for research purposes was banned during a moratorium, and both Acts were scheduled for review by the end of 2005. Accordingly, a six-member independent legislative review committee (LRC) was convened in June 2005. The LRC's mandate was to review the scope and operation of existing legislation, particularly in light of developments in technology in relation to assisted reproductive technologies (ART), medical and scientific research, the potential therapeutic applications of such research, and changes in community standards since 2002. The LRC also was asked to consider the applicability of establishing a national stem cell bank and the effectiveness of monitoring and compliance schemes, such as licensing provisions.

Following processes for public engagement (discussed below), the LRC recommended a continued prohibition of (1) human reproductive cloning; (2) implantation for reproductive purposes of human embryos created by nuclear transfer or means other than fertilization of egg by sperm; and (3) implantation of animal embryos into humans or human embryos into non-human animals. It also recommended continued use of excess ART embryos for research subject to certain licensing conditions, and the establishment of a national stem cell bank. More controversially, the LRC expressed support for somatic cell nuclear transfer, or therapeutic cloning and transfer of human somatic cell nuclei into non-human animal oocytes to create chimeric embryos for research, as well as a number of other alternative techniques for creating human embryos. All of these permitted procedures required licenses from the NHMRC and placed a 14-day limit on development of such embryos before destruction (Australian Government 2005). The report was presented to the Minister for Ageing, the Hon Julie Bishop MP, on 19 December 2005 and was immediately referred for tabling in both Houses of Parliament and for presentation to state health ministers.

The LRC was explicitly required to consult with the Commonwealth, State, and Territory governments and "a broad range of people with expertise or experience in

relevant disciplines", a mandate addressed through written submissions and invited testimony on the scope and operation of the two Acts (LRC 2005c). In its reports, the LRC described the various stages and types of expert and public engagement as follows:

- Establishment of a website, containing information about the review, its terms of reference and membership, details about public meetings, posting of an Issues paper (LRC 2005a), relevant links to the existing legislation, and an invitation to make a submission to the review.
- Collection and review of 1035 written submissions.[2]
- Public hearings in each State and Territory capital (except Hobart where a video-conference was held) including open meetings and some confidential hearings with invited stakeholders, as well as facilitated discussion forums for stakeholders in Brisbane, Sydney, and Melbourne.
- Private meetings with State and Commonwealth government ministers, government department representatives, and the Embryo Licensing Committee of the NHMRC.
- Site visits to Sydney IVF, a research centre at Monash University, and the Australian Stem Cell Centre.
- Media releases and coverage of the hearings.
- A commissioned research paper and literature review, provided by the Minister of Ageing, drawn from an NHMRC discussion paper on the biological definition of the human embryo.
- Preliminary findings of a study of Australian attitudes towards stem cell research based on focus group discussions and telephone surveys undertaken by Biotechnology Australia's Public Awareness Program.

In its 256-page report, the LRC indicated that it sought to reflect the range of views expressed through the public engagement processes noted above. In addition, there are signs of attention to the need to engage in a policy process that could have deliberative, participatory, and justificatory legitimacy though the process was more successful in terms of some criteria than others. For example, although attempts were made to seek direct input from stakeholders, notably via calls for written public submissions, the structure of the process tended to privilege expert views as well as those of pre-identified and well-organized community groups, particularly those taking religious perspectives. Although the LRC report makes extensive use of quotations from a number of submissions, contributions by researchers, clinicians, ethicists, representatives of religious organizations, and government agencies are disproportionately quoted. Hence engagement was less inclusive than it might have been, as there were few opportunities for participation by those not already identified as "stakeholders" except in a limited manner through Biotechnology Australia's studies of public attitudes. In regard to deliberative processes, these were almost non-existent, and largely reflected so-called "passive" consultative processes (see McGurk *et al.* 2006, p. 810).

On the criterion of the critical promotion of public understanding of science, however, the LRC process was quite successful, in as much as it published an Issues paper which

was generally in plain English and which provided relevant detailed scientific and technological information, including noting disagreements or gaps in knowledge within the field, in advance of seeking public submissions. There also were facilitated discussions among stakeholders in some cities, which allowed arguments and ideas to be openly pursued. But while these sessions had potential to foster discursive participation, as well as create conditions for deliberation, experts primarily attended them and they were limited in duration and scope.[3] As was the case with the issues outlined in the call for public submissions, the discussion topics structuring these sessions were not open-ended but were directly tied to the LRC's limited mandate. They related particularly to the scope and operation of the Acts with respect to new technological developments since the implementation of the original Acts (LRC n.d.).[4] The limited number and types of participants led to conversations that generally focused on debate about the definition of the embryo in the LRC's Issues paper. On the positive side, the facilitated discussions used hypothetical scenarios to highlight points of disagreement, encouraged interchange between participants, and seemed to be aiming not to reach definitive conclusions but to air arguments and concerns.

The LRC itself, based on its report and first-person accounts by participants (Skene 2007), claims that discursive participation and respectful deliberation were prioritized. However, it is unclear whether there was anything inherent in the mandate or structure of the process that would have fostered these processes. Attention to creating conditions for deliberation instead may have occurred because of the background and expertise of members of the LRC, several of whom were well versed in bioethics and/or legal negotiation and mediation. The limited amount of time permitted for public engagement as well as the highly structured framing of the debate meant that there also were limited opportunities for developed or iterative deliberative processes, for instance in comparison to some of the Australian Law Reform Commission processes.

The LRC process performed reasonably well in terms of the criteria for review of the deliberative processes for contestable legitimacy. An explicit recommendation of the need for re-review was made, along with a recommendation for continued public education in the relevant areas of science. Although re-review might provide opportunities for public engagement, the latter recommendation seems to endorse a unidirectional form of science communication, the so-called "deficit model" of public understanding of science (Wynne 1991, Ziman 1991), which often in practice does not invite participation or deliberation. However, the process could be seen as going a considerable way towards fulfilling the criterion of contestable justification. The LRC report included both the outcomes of the processes of public engagement and justifications for the policies proposed including their underlying reasoning for recommendations and an assessment of the difficulties in the process, particularly the complexities of engaging various publics. For instance, it detailed many issues that the LRC encountered in attempting to address its terms of reference, including the need to assess the Acts in the light of "developments in community standards", as it found "that the social and moral concerns raised by ART and embryo research could not be explained simply by reference to a single

'standard' or set of values, beliefs or interests held by a single community" (2005c, p. 161). Nonetheless:

> In looking for common ground, the Committee noted that there are certain moral values that are held in common by all communities, such as a commitment to social justice and equity, and to the care of vulnerable members of society ... Hence the Committee came to the view that consideration regarding the use of embryos for research needed to take account of both the value that different communities attach to the embryo, and the social and moral value that communities attach to the treatment of disease and the amelioration of infertility. (ibid.)

The LRC report clearly noted the diversity of views expressed, but also that:

> Each of these views is sincerely held and it was apparent to the Committee that all those who made submissions were motivated by a desire to do what is best for our society. However it was also clear to the Committee that these views could not always be reconciled. (ibid.)

The report thus sought to explain how the LRC worked its way through the moral morass of conflicting and non-reconcilable views to generate its recommendations. In framing the recommendations, the LRC considered that the higher the potential benefits of an activity, the greater the need for ethical objections to be of a high level and widely accepted in order to prevent the activity (ibid., p. 162). Procedurally, this claim is crucial as it attempts to make explicit the reasoning used, although there are a number of definitional problems inherent in this weighing exercise, notably, how benefit and harm are to be measured, by whom, and so on. In particular, the relative weight assigned to the claimed benefits of human embryonic stem cell research relative to ethical objections about such research was the key argument used to support the LRC's recommendations in favor of the use of "excess" ART embryos for research, as well as the use of somatic cell nuclear transfer and the creation of chimeric embryos for research.

The embryo research conscience votes

In Australia, federal parliamentarians are expected to vote according to pre-existing party policy or under instructions from party elites. A conscience vote, or a "free" vote as it is sometimes known, occurs on a Bill, Motion, or Report either because a political party does not have a policy position on an issue or because the party decides that members should be "permitted to exercise their responsibility in accordance with conscience" (Harris 2001, p. 277). In such cases, "members are not obliged by the parties to follow a party line, but vote according to their own moral, political, religious, or social beliefs" (Penguin 1988, p. 86).

Permitting a conscience vote is a pragmatic way of addressing divisive policy questions, and accommodating diverse moral or ethical views within the party. This is because a conscience vote is preferable to members voting against party policy and "crossing the floor". Conscience votes encourage an increased level of public engagement, lobbying, and deliberation, which suggests that in these cases parliamentarians may be more informed than otherwise. Thus, they are more likely to attend to the

views expressed by their constituents and to be moved by the arguments of their parliamentary colleagues without regard to the party of the person making the argument. Voters may have good reason to believe that their efforts at persuasion of their elected representatives will be more effective where the representative has the freedom of a conscience vote. Further, there are additional pressures on elected representatives for transparency regarding the reasoning underlying particular decisions, so that outcomes can be recognized by citizens as having been fairly decided and informed by citizen responses to the issues. For these reasons, conscience votes *may* enhance deliberation and accountability within a Parliament.

In the case of embryo research, the existing Bills, together with the LRC recommendations were put on the parliamentary agenda for debate in 2006. Discussion centered on the more controversial proposals in support of somatic cell nuclear transfer and the creation of human–animal chimeras for experimentation. Limits imposed on research under the Bill included strict prohibitions on the implantation of cloned embryos into a woman and on allowing cloned embryos to develop beyond 14 days. There was also a requirement that the NHMRC develop "objective" criteria for determining when a human embryo is unsuitable for implantation. The debates garnered considerable media attention, and interchanges between members of the electorates and their representatives were documented in Hansard, along with the debates themselves. All major parties announced that they would permit conscience votes on any legislative changes that might be proposed.

Democrat Senator Natasha Stott Despoja and Labor Senator Ruth Webber subsequently tabled a draft Bill incorporating all of the LRC recommendations for discussion. Later, a more conservative Bill, the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 was introduced as a private Senator's Bill by Liberal Senator Kay Patterson in mid-October 2006. Following amendments (including removal of permissibility of chimera research), the Bill passed through Senate on 7 November 2006 in a close conscience vote: 34 in favor and 32 against. The final conscience vote in the House of Representatives was not recorded although it passed "on the voices" on 6 December 2006 (Anon 2006). Opposing the Bill were three Liberal Ministers (Health Minister Abbott, Treasurer Peter Costello, and Employment Minister Kevin Andrews), the Liberal Prime Minister Howard, and the freshly elected Labour opposition leader Kevin Rudd (elected Prime Minister in late 2007). They cited their personal moral objections to the Bill (Anon 2006, Burke 2006, King 2006). An appeal to "conscience" was also the motivation for some of those supporting the Bill, with Liberal Education Minister Julie Bishop saying: "I cannot in all conscience stand in the way of the only ray of hope available to sufferers of devastating and debilitating disease and injury" (King 2006).

In terms of the characteristics necessary for legitimacy, the processes associated with the parliamentary conscience votes on embryo research score fairly well in terms of what actually occurred. Among a number of senators, direct input from the electorate was actively pursued and received, and the reasoning underlying people's views was assessed, although the process itself did not in any way guarantee either of these.

Similarly, although neither required nor guaranteed by the process, there is evidence in Hansard that many parliamentarians sought detailed information about scientific and social issues associated with embryo research through consultation with a range of experts, including those who participated in the LRC. However, the parliamentary conscience vote process did not create opportunities for inclusive engagement, as engagement was reduced to the usual forms of political representation and heavily privileged the positions of established "experts", including the LRC members. Nor did it explicitly seek to create conditions for respectful deliberation, though some level of public trust may have been engendered by the relative transparency of the parliamentary processes. Transcripts in Hansard and informal reports indicate that a number of politicians attempted to justify their positions and to make explicit their underlying rationales (see Australian Senate 2006). Senators Bartlett, Wong, and Colbeck, to pick three, each commented on the quality of the debate, the reasoning used in reaching their own positions and, as Senator Bartlett indicated, the particular importance for legislators to attend to the substance of the arguments in this debate: "Given the importance of the issue before us, we need to examine more the substance of the arguments that need to be considered" (Australian Senate 2006, p. 16). However, as the ultimate output of this type of process is a vote on legislation rather than a justificatory process, there were few opportunities for detailed justification of the outcomes and hence limited possibilities to fulfill the criterion of contestable justification. The need to review the Bill over time was explicitly noted.

NHMRC guidelines

The Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 was slated to come into effect on 12 June 2007, and as part of its mandate, the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) was required to review and revise its existing guidelines concerning embryo research – the 2004 *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*.[5] The inclusion of the NHMRC and AHEC in the embryo research regulation process is recognition of the distinction between law and ethics; that what is ethically desirable (or reprehensible) should not necessarily be directly reflected in law, and that the law is a relatively "blunt instrument" so further ethical guidance and interpretation is typically required following the introduction of legislation.

In 1998, following evidence of the potential for cloning technologies, AHEC had proposed that all States and Territories introduce legislation to regulate and limit research on human embryos based on the NHMRC guidelines (1996). The AHEC explicitly recommended that the Health Minister should foster "informed community discussion" on the potential risks and benefits of cloning technologies (AHEC and NHMRC 1998, p. 43). In response, the 2001 Andrews Report noted that AHEC should be charged with "developing and implementing a strategy to consult and involve the public in consideration of the issues arising from this research and encourage debate on the potential

and implications of the research" (Andrews Report 2001, p. xx). However, the National Health and Medical Research Council Act (1992) only explicitly requires a public consultation process on guidelines for human research that "has regard for" submissions, without further details about what the process should include. For instance, it provides no details as to what would count as critical evaluation or assessment of submissions in relation to the matter at hand, as opposed to merely reading and noting submissions.

In mid-April 2007, the NHMRC issued a consultation draft of AHEC's revisions to the existing ART guidelines, including guidelines directly related to embryo research as well as so-called objective criteria for determining when a human embryo is unsuitable for implantation, and hence potentially eligible for research. The NHMRC requested public submissions on these draft guidelines within one month. The original draft document focused on providing ethical guidance concerning processes and consent for human egg and embryo donation, and concerning research on human embryos deemed unsuitable for implantation and those created by somatic cell nuclear transfer. However, the original document did not appear to fully recognize some aspects and implications of the new legislation. For instance, at times it made it sound as though some research practices (for example, somatic cell nuclear transfer) were still prohibited even if they could be pursued with a license. It also failed to mention explicitly any of the processes through which the revised guidelines were produced. As a consequence of the tight timeframe and what was fairly limited publicity, a total of 93 submissions were received.

Of the submissions made public, 40% were from individuals and 60% were from organizations, including research institutes and ART clinics, religious and women's organizations, and disability or illness support groups. The final revised guidelines were completed as required by mid-June 2007, and reflected minimal changes to the existing 2004 document (NHMRC 2007). An examination of the processes surrounding the production of the revised NHMRC guidelines by AHEC in terms of the characteristics necessary for legitimacy reveals that both the formal requirements for the process and the actual processes in which AHEC engaged were very limited. Direct public input occurred only via responses to the standard call for written submissions, and the response rate was extremely low due in part to the deadline imposed as well as limited publicity about the call for submissions. There is no evidence of any attempt to promote critical public understanding of science either within AHEC's own processes or externally, though there may have been an implied dependence on the promotion of public understanding of science that occurred in the LRC and parliamentary processes. There is also no evidence of overt attempts to broaden inclusive engagement, since, as already noted, public engagement was limited to written submissions.

More explicitly, AHEC's mandate does not foster discursive participation, as it only requires "having regard to" any public submissions made, and there is no evidence in AHEC's documents of any further processes of reasoning or exchange that would fulfill the requirements for discursive participation. The lack of transparency in AHEC processes thus poses an impediment to the conditions for creating public trust. The final document primarily reflected changes needed to make the guidelines consistent with the legislation. It is unclear whether the consultation process allowed participation

beyond the articulation of opinions. Similarly, with regard to the criterion of contestable justification, there was no information about how AHEC came to its conclusions or how they weighed public contributions. The documents issued focused only on outcomes rather than any justifications for the recommendations. Finally, the process fares poorly with regard to the criterion of the need for review over time, as there was no explicit discussion of when, or under what conditions, AHEC might need to review the guidelines.

Reflections on the role of public involvement in future deliberative governance processes

In many respects the forms of public engagement we have outlined above are consistent with what Irwin has identified as "unsubstantiated words and empty rhetoric" (Irwin 2006, p. 318). Despite apparent general goodwill on the part of the committees and parliamentarians to engage various publics in most stages of the processes associated with the governance of human embryo research in Australia in 2005–2007, structural issues and other impediments undermined the promise of "public engagement". These limitations are important to consider for future life sciences policy development in Australia given the current dynamic of strong governmental promotion of biotechnology investment, which occurs alongside vigorous questioning of, and opposition to, certain technologies by various communities, particularly religious groups. Examination here of attempts to reconcile demands of concrete policymaking in real time with the goal of honoring significant differences in strongly held values suggests likely difficulties in relying on policy-recommending committees such as the LRC to resolve differences in the absence of a culture of public deliberation and specific expertise on how to foster deliberative processes. Depending heavily on written submissions provided within minimal timeframes, privileging expert testimony, and emphasizing representative processes may well result in the exclusion of many relevant stakeholders. Some may believe they do not have a stake in the issues under debate, until it is brought to their attention through the fostering of deliberative opportunities.

In all three stages of the policy development process examined in this paper, there were prohibitive timelines, limiting the amount of participation in which participants could engage, as well as minimal deliberative processes for engaging various publics.[6] In both the LRC and AHEC processes, there also was a lack of clarity about how public engagement and deliberations might shape or change the outcomes, or whether they were largely pro forma processes which ultimately would be subservient to the parliamentary ones. The pre-framing of the scope of debate limited inclusion of certain arguments and presupposed certain forms of reasoning as acceptable.[7] For example, only changes in public views since 2002 were to be considered by the LRC, which raised concern among a number of stakeholders. Finally, the processes tended to be reactive to public opinions expressed rather than creating conditions for inclusive deliberation.

These limitations indicate that there is a need to trial different mechanisms beyond calls for submissions to enhance both the quality and quantity of direct input from a variety of

publics, as well as to ensure different types of fora for formal and more informal public engagement.[8] These mechanisms should seek not only to elicit public opinion but also to foster cultures of respectful deliberation and debate, in addition to allowing for ongoing promotion of critical public understanding of science without privileging expert scientific knowledge. In turn, there should be more engagement of those traditionally viewed as non-experts as well as those typically or systematically excluded in current processes.

There are good reasons for being cautious about "institutional claims to have embraced a new social contract of dialogue, transparency and consultation", as Irwin has noted with respect to his evaluation of policy processes associated with genetically modified organisms in the United Kingdom (2006, p. 302). Australian attempts to "engage the public" in policy development relating to human embryo research provide another excellent example of the need for this caution and for better "scientific understanding of publics", or for recognition that public mistrust of science is much more complex than a simple matter of ignorance (Wynne 2006). This Australian case study highlights the ways in which rhetoric may exceed processes for public engagement and how existing regulatory structures can impose real limitations on public engagement with policy development in real time, indicating that more proactive processes are needed. This case study also illustrates that public engagement with science and technology has become highly political, as a variety of actors, including legislators, increasingly recognize public views as an important source of legitimation for their positions.

Perhaps the most striking lesson for life sciences governance in Australia is the need to recognize that the framing of contentious issues and of public engagement itself significantly affects who participates and who is considered a "relevant" stakeholder. More attention is needed to promoting transparency and accountability in governance processes, as otherwise public trust will not be achieved or maintained. Finally, few formal mechanisms currently exist for providing reasons for policy decisions. Such mechanisms are necessary to foster deliberation and for any useful review over time of policy, given the rapidly changing nature of these technologies. In the absence of careful consultation and engagement allowing public participation to be informed and critical, we cannot reliably claim to know which groups within the community are most concerned about a particular issue and why. In sum, any policy processes seeking public engagement about highly contentious life sciences issues need to be inclusive and provide appropriate information about the issues under discussion. Attention to these issues will better ensure that all those affected have effective voices in what should be a deliberative process, not solely those who have been best able to express their concerns in the past. Such deliberative processes are a critical part of the process of rethinking political and national identities and the development of new trajectories for life sciences governance.

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Notes

1. The Prohibition of Human Cloning Act passed through the Senate with just a slim majority, while the Senate unanimously passed the Research Involving Human Embryos Act (for the history of embryo research regulation prior to this time, see: Chalmers 2002, Nicol *et al.* 2002, Hall 2004, Harvey 2005, Dodds and Ankeny 2006).
2. Of these, the majority (921) were from private individuals. In addition, 98 were from organizations, eight from government agencies, and eight from individual parliamentarians. The LRC also received nine different "form letters", of which eight with 898 signatures in total advocated a ban on human cloning and/or human embryo research and one with 378 signatures supported human embryonic stem cell research.
3. Academics were well represented in Brisbane and Sydney. In Melbourne, there were also carers and people with conditions that might be treatable using stem cell therapies as well as a number of pro-life organization representatives (see LRC 2005c, Appendix; LRC 2005b).
4. This related to developments in assisted reproductive technology, and developments in medical and scientific research for the treatment of human diseases. There was also the possible establishment of a National Stem Cell Bank (LRC n.d., p. 2).
5. These were revised after information about the production of Dolly the sheep using cloning technologies become public in 1997. The Commonwealth government requested more detailed advice on cloning from AHEC, including recommendations for a regulatory model to align with international developments.
6. It is arguable that other bodies which examine similar controversial issues in life sciences governance, but which have different mandates and tend not to be legislative, more effectively attend to establishing and fostering processes and frameworks for deliberation, such as the Australian Law Reform Commission and the New Zealand Bioethics Council.
7. See Harvey (2008, p. 37) for further discussion of the ways in which this debate was circumscribed.
8. For example, the processes followed by the Canadian Royal Commission on New Reproductive Technologies of the Australian Law Reform Commission and AHEC report on genetic privacy.

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